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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/698,121      | 10/30/2000  | Jerome Aucouturier   | 746200-000062       | 5877             |

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/13/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/698,121

Applicant(s)

Aucouturier et al.

Examiner

G. R. Ewoldt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Oct 2, 2001

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-32 is/are pending in the application.

4a) Of the above, claim(s) 1-18 and 21-29 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 19, 20, and 30-32 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 20)  Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's election with traverse of Group V (claims 19-20 and 30-32) and the species "composition H", in Paper No. 9 is acknowledged. The traversal is on the grounds that an examination of all groups and species would not pose a serious burden on the Examiner as some of the inventions are classified in the same classes and subclasses.

These arguments are not found persuasive for the following reasons. While the searches of the related inventions may overlap, and provide some relevant art, the fields of search are different and not coextensive, even though some of the inventions might be classified in the same classes or subclasses. Further compositions comprising different components, as well as methods employing said compositions, comprise patentably distinct inventions, the searches of which are not coextensive. Thus, the instant search has been found not to be coextensive for multiple reasons. One method of demonstrating undue burden is to demonstrate that the searches of the claimed inventions are not coextensive; thus, the searches of Groups I-VI are found to pose an undue burden on the Examiner because they are not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-18 and 21-29 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 19-20 and 30-32 are being acted upon.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 19-20 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements critical or essential to the practice of the invention, but not included in the claims are not enabled by the disclosure. The instant claims recite a method of providing an adjuvant effect employing a vaccine, said vaccine comprising an antigen and an adjuvant composition that is asserted to be novel for said

use. As such, the description of the adjuvant composition, as well as methods for identifying other compositions that might fall within the scope of the genus of said adjuvant compositions employed in the instant claims, would be considered essential to the instant invention. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The elected species of adjuvant is disclosed only as "composition h". It is unclear from the disclosure of the specification, however, just what "composition h" consists of. The Table on page 9 of the specification appears to indicate that "composition h" comprises some sort of "mannitan oleate". The Table also seems to indicate at least nine other "mannitan oleates," thus, it is unclear how "composition h" differs from "compositions" e-f and i-o. Note that some of the compositions seem to comprise a particular number of "EOs," however, "EO" is not defined in the specification.

Also note that it is apparent that the calculation of "HLB" numbers is essential to the claimed invention. However, for the calculation of said numbers the specification merely refers to "the European Pharmacopoeia." Said reference is improper and comprises a further absence of essential material.

5. No claim is allowed.

6. All references on Applicant's Form 1449, submitted 10/30/00, have been lined through and have not been considered because the references are in French.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.  
Patent Examiner  
Technology Center 1600  
December 12, 2001

*Patrick J. Nolan*

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